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MERCK FROSST CANADA & CO.,
MERCK CANADA INC., and
MERCK SHARP & DOHME PHARMACEUTICALS

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MERCK FROSST CANADA & CO., MERCK CANADA INC., and MERCK SHARP & DOHME PHARMACEUTICALS, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC. Defendants.	CIVIL ACTION NO.:____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Merck Frosst Canada & Co., Merck Canada Inc., and Merck Sharp & Dohme Pharmaceuticals (collectively, "Plaintiffs") by way of Complaint against Dr. Reddy's Laboratories, Ltd. ("DRL India") and Dr. Reddy's Laboratories, Inc. ("DRL USA"), alleges as follows:

THE PARTIES

1. Plaintiff Merck Frosst Canada & Co. is a corporation organized and existing under the laws of Canada, having a principal place of business at 16711 TransCanada Highway, Kirkland, Quebec H9H 3L1.

2. Plaintiff Merck Canada Inc., formerly Merck Frosst Canada Ltd., is a corporation organized and existing under the laws of Canada, having a principal place of business at 16711 TransCanada Highway, Kirkland, Quebec H9H 3L1.

3. Plaintiff Merck Sharp & Dohme Pharmaceuticals, formerly Merck Sharp & Dohme Pharmaceuticals SRL (Barbados), is a restricted liability company organized under the laws of Bermuda, with offices at Clarendon House, 2 Church Street, Hamilton HM11, Bermuda.

4. On information and belief, DRL India is a corporation organized under the laws of India, having its headquarters at 7-1-27 Ameerpet, Hyderabad, Andhra Pradesh 500 016, India.

5. On information and belief, DRL USA is a corporation organized and existing under the laws of the state of New Jersey, having its headquarters at 200 Somerset Corporate Boulevard, 7th Foor, Bridgewater, NJ 08807.

6. On information and belief, DRL USA is a wholly-owned subsidiary of DRL India, and operates as the authorized U.S. agent of DRL India with respect to Abbreviated New Drug Application ("ANDA") No. 202906.

7. On information and belief, DRL USA and DRL India (collectively, "DRL") are in the business of developing and manufacturing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over DRL USA because DRL USA resides in this judicial district and has continuous and systematic contacts with the state of New Jersey.

10. On information and belief, DRL USA acts under the direction, control, and influence of DRL India with respect to the acts and conduct alleged in this Complaint. DRL USA's continuous and systematic contacts with the State of New Jersey, as an agent of DRL India, are attributable to DRL India for jurisdictional purposes. Additionally, DRL India is the named applicant for ANDA No. 202906, which it submitted to the U.S. Food and Drug Administration ("FDA") by and through its U.S. agent, DRL USA.

11. For the reasons set forth above, this Court has personal jurisdiction over DRL India.

12. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and/or 28 U.S.C. § 1400(b).

MERCK'S NDA AND ASSERTED PATENT

13. Merck Research Laboratories, a division of Merck & Co., Inc. ("Merck"), filed New Drug Application ("NDA") No. 021409, by which the FDA granted approval for Montelukast Sodium Oral Granules Eq. to 4 mg Base/Packet. The montelukast sodium

formulation described in NDA No. 021409 is approved for the treatment of asthma in pediatric patients. Montelukast Sodium Oral Granules Eq. to 4 mg Base/Packet is sold by Merck under the tradename "SINGULAIR®".

14. Plaintiffs own all right, title, and interest in U.S. Patent No. 8,007,830 (the "'830 patent"), which is attached as Exhibit A.

15. Pursuant to 21 U.S.C. § 355(b)(1), Merck has submitted information concerning the '830 patent to the FDA in connection with its NDA No. 021409, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

DRL'S ANDA AND NOTICE LETTER

16. By letter ("Notice Letter") dated January 13, 2012, and received on January 18, 2012, DRL gave notice that it had submitted ANDA No. 202906 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use and sell generic Montelukast Sodium Oral Granules Eq. to 4 mg Base/Packet (the "DRL Generic Product") prior to the expiration of the '830 patent.

17. In the Notice Letter, DRL informed Merck Frosst Canada & Co. and Merck & Co., Inc. that its ANDA contained a "Paragraph IV Certification" that the '830 patent will not be infringed by the manufacture, use, sale, offer for sale or importation into the United States of the DRL Generic Product.

18. This complaint for patent infringement is being filed before the expiration of forty-five days from the date Merck Frosst Canada & Co. and Merck & Co., Inc. received the DRL Notice Letter.

INFRINGEMENT OF THE '830 PATENT

19. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-18.

20. DRL's filing of ANDA No. 202906 with the FDA to obtain approval under the Federal Food, Drug, and Cosmetic Act for the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its DRL Generic Product before the expiration of the '830 patent constitutes an act of infringement under 35 U.S.C. § 271(e)(2)(A).

21. DRL's commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of its DRL Generic Product before the expiration of the '830 patent will constitute direct infringement, active inducement, and/or contributory infringement of the '830 patent under 35 U.S.C. § 271(a), (b), and/or (c), respectively.

22. DRL was aware of the existence of the '830 patent and was aware that the filing of its ANDA and certification with respect to the '830 patent constitutes an act of infringement of that patent.

23. Plaintiffs will be substantially and irreparably harmed if DRL's infringement of the '830 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

24. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of DRL's ANDA be a date that is not earlier than the October 24, 2022, expiration date of the '830 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

25. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

26. Plaintiffs request that:

a. Judgment be entered that DRL has infringed the '830 patent by submitting ANDA No. 202906;

b. Judgment be entered that this is an exceptional case, and that Plaintiffs are entitled to reasonable attorney fees pursuant to 35 U.S.C. § 285;

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining DRL, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of drug compounds claimed in or the use of which is claimed in the '830 patent;

d. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 202906 be a date which is not earlier than the later of October 24, 2022, the expiration date of the '830 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled; and

e. For such other and further relief as the Court may deem just and proper under the circumstances.

Dated: March 2, 2012

Respectfully submitted,

By: s/ Sheila F. McShane

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